DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 5, 2014

Toshiba Medical Systems Corporation, Japan
% Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K133324
Trade/Device Name: SURE Subtraction Lung (CSSL-001A)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: August 5, 2014
Received: August 6, 2014

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K133324

Device Name

SURESubtraction Lung; CSSL-001A

Indications for Use *(Describe)*

SURESubtraction Lung software is intended to aid in the visualization of lung parenchyma enhancement by subtracting a non-contrast enhanced volume from a contrast enhanced volume.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SUBMITTER'S NAME:**
   Toshiba Medical Systems Corporation

2. **ADDRESS:**
   1385 Shimoishigami
   Otawara-shi, Tochigi 324-8550, Japan

3. **ESTABLISHMENT REGISTRATION:**
   9614698

4. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000
   2441 Michelle Drive
   Tustin, CA. 92780-2068

5. **DATE PREPARED:**
   August 4, 2014

6. **TRADE NAME(S):**
   SURESubtraction Lung, CSSL-001A

7. **COMMON NAME:**
   System, X-ray, Computed Tomography

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750)

9. **PRODUCT CODE / DESCRIPTION:**
   90JAK – System, Computed Tomography

10. **PERFORMANCE STANDARD:**
    None

11. **PREDICATE DEVICE:**

Product	Marketed by	510(k) Number	Clearance Date
Aquilion ONE Vision, TSX-301C/1, v4.90	Toshiba America Medical Systems	K122109	September 21, 2012

12. REASON FOR SUBMISSION:

This submission is to report changes to the current subtraction software that exists on the predicate device. The change is to provide a subtraction software that is dedicated to subtraction of lung volumes. These changes do not affect the intended use of the predicate which is to provide visualization of contrast enhancement as the result of subtraction.

13. DEVICE DESCRIPTION:

The SURESubtraction Lung, CSSL-001A, is a post-processing software that subtracts image information by comparison of two data sets, one of which is contrast enhanced. Registration software is used to match the two independent studies. A similar registration software has been used on Toshiba CT systems for a number of years with no adverse events reported.

14. INDICATIONS FOR USE:

SURESubtraction Lung software is intended to aid in the visualization of lung parenchyma enhancement by subtracting a non-contrast enhanced volume from a contrast enhanced volume.

15. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to SURESubtraction, the subtraction tool used for Orbital Synchronized Scan System, CKOS-001A, which was originally cleared under the premarket notification for TSX-101A/H, /I, Aquilion 64/32 SP CT Scanner 510(k), K051833. Since this clearance, all Toshiba CT systems have incorporated this post processing software; the latest clearance being on the Aquilion ONE Vision, TSX-301C/1, v4.90, K122109.

SURESubtraction Lung includes modifications to the predicate software which improves on the anatomical region with which the software can be used. A summary of the changes is included below and in more detail within this submission.

	SURESubtraction, CKOS-001A	**SURESubtraction Lung, CSSL-001A**
	Predicate device	Subject Device
Anatomical Region (CT Field Of View)	Head and neck region	Lung
Target For Subtraction	Bone and calcifications close to vasculature	Lung Tissue
Spatial Resolution of Deformation Field	Same As Image Resolution	Same as Image Resolution
Degree of Allowed Deformation	Adjusted to Bone Object	Adjusted to Lung
Local Refinement	Calcification Region (Optional)	All Values in Lung Region

16. SAFETY:

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC62304 and IEC62366 standards. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report.

17. TESTING

Risk analysis and performance testing conducted through bench testing are included in this submission which demonstrates that the resultant subtraction images produced by the software can be used in the visualization of abnormal blood perfusion correlating to thromboembolic disease such as pulmonary embolism. .

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

Testing was conducted by evaluation of the software on clinical data at an investigational site. This data concluded that the software aids in the visualization of contrast enhancement.

18. CONCLUSION

SURESubtraction Lung, CSSL-001A, performs in a manner similar to the predicate device in that subtraction images are created which aid in diagnosis. Based upon the data presented in this submission including conformance to standards, application of design controls and performance data, Toshiba America Medical Systems, believes that SURESubtraction Lung, CSSL-001A, is substantially equivalent in safety and effectiveness to the predicate device.